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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/614,741

07/07/2003

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S16.12-0136

6207

27367 7590 06/30/2008  
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EXAMINER

GANESAN, SUBA

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

06/30/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/614,741	<b>Applicant(s)</b> ANDERSON ET AL.	
	<b>Examiner</b> SUBA GANESAN	<b>Art Unit</b> 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 20, 22-24, 26, 27 and 30-38 is/are pending in the application.
- 4a) Of the above claim(s) 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20, 22-24, 26-27, 30-34, 37-38 is/are rejected.
- 7) ☒ Claim(s) 36 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the Claims***

Claims 20, 22-24, 26-27 and 30-38 are currently pending.

### ***Response to Arguments***

1. Applicant's arguments with respect to claims 20, 22-24, 26-27 and 30-38 have been considered but are moot in view of the new ground(s) of rejection.

### ***Allowable Subject Matter***

1. Claim 36 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 20, 22-24, 26-27 and 30-34, 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (5,449,384) in view of Williamson IV et al (6,402,780).

2. Johnson discloses a method for attaching a stentless porcine heart valve prosthesis comprising inserting fasteners 708, 710, 712 (sutures) through the prosthesis and through an aortic wall 700 (fig. 17). The prosthesis comprises leaflets 724,726,728 with commissure supports 110,112,114 and reinforcements 120,122,118 positioned along an inner surface of at least one of the commissure supports. Note that the phrase “positioned along an inner surface” does not require the reinforcements and commissure supports to be separate elements. Therefore the reinforcements 120,122,118 are considered to be “positioned along an inner surface” of commissure supports 110,112,114 because they share an inner surface. The reinforcements include an aperture (Fig. 2). The fastener is inserted through the aperture and into the aortic wall (See fig. 17). However Johnson fails to show fastener having a head and barbed tip. Williamson IV et al teaches the use of a fastener having a head and sharp barbed tip (e.g. Fig. 65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of a fastener having a head and tip, as taught by Williamson IV et al, to a method as per Johnson, the fasteners of Williamson IV et al being capable of connecting vascular tissues or implants to tissues (see abstract) in situations where the use of sutures would be more difficult (col. 2, lines 5-18). See Williamson IV for various fastener types.

3. With respect to claim 34, the reinforcement of Johnson can alternatively be considered to be “along the outer surface of the prosthesis” since the reinforcements 120,122,118 are located on the outer edge of the prosthesis (see fig. 16-17). The fasteners are inserted along a curvilinear path (at the three commissure locations)

***Conclusion***

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUBA GANESAN whose telephone number is (571)272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3774

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. G./

Examiner, Art Unit 3774

/William H. Matthews/

Primary Examiner, Art Unit 3774